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EXAMINER

SEVERSON, RYAN J

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/674,026

Applicant(s)

SWAYZE ET AL

Examiner

Ryan Severson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-15 and 18-20 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 13, 16, and 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/29/2003</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "278" and "298" have both been used to designate the "biasing wheel" (see Figures 8 and 9). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "670" has been used to designate both a "curved tooth segment" and an unidentified external handle portion (see Figure 29). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application.
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 72, 176 and 500 (see Figures 4, 26 and 27). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application.
4. The drawings are objected to because of the following minor informalities:
  - The E-Beam disclosed on page 11, line 4 of the specification references number 82, but should be 80 as is consistent with the rest of the description and the drawings.

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- In Figure 23, reference numeral "24" should be corrected to read "42" to maintain consistency with the specifications and drawings describing the "anti-backup release button."
- Also in Figure 23, reference numeral "433" should be corrected to read "432" to maintain consistency with the specifications and drawings describing the "indicator pin."
- In Figure 22, reference numeral "432" is used twice, pointing to two separate parts.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application.

Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required

corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37 CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

### ***Claim Objections***

5. Claim 16 objected to because of the following informalities: It is suggested the claim should be correct to read "The surgical instrument of claim 15, wherein the indicator member comprises a gear having ~~a~~ at least one dwell area and gear section, the gear section engageable to the firing mechanism." Appropriate correction is required.
6. Claim 13 is objected to because of the following informalities: It appears claim 3 was inadvertently copied and pasted onto the end of claim 13 (see Claim 13, Lines 14-16). The sentence " 3. The surgical instrument of claim 2, wherein the handle further comprises a housing and the indicator member includes a knob exposed by the housing" Appropriate correction is required." will not be considered as included in claim 13. If applicant would like this sentence to be included in claim 13, the entire claim 13 must be written as a single sentence.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7-9, and 13-19 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "the indicator gear" in line 3 of claim 7. There is insufficient antecedent basis for this limitation in the claim.

Claim 8 recites the limitation "said end effector" in line 1 of claim 8. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "said end effector" in line 1 of claim 9. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 also recites the limitation "said shaft" in line 2 of claim 9. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 also recites the limitation "said firing member" in line 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "the indicator member" in lines 15-16 of claim 13. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "the knob" in line 2 of claim 14. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "the indicator member" in line 1 of claim 15. There is insufficient antecedent basis for this limitation in the claim.

Claim 16 recites the limitation "the indicator member" in line 1 of claim 16. There is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "the indicator gear" in line 3 of claim 17. There is insufficient antecedent basis for this limitation in the claim.

Claim 18 recites the limitation "said end effector" in line 1 of claim 18. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "said end effector" in line 1 of claim 19. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 also recites the limitation "said shaft" in line 2 of claim 19. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Milliman et al. (5,865,361). Milliman et al. reference discloses a surgical stapling apparatus comprising an "elongate implement portion" (14, 16 and 17) and a handle comprising a "firing mechanism" (46), a "firing trigger" (24), and an "indicator member" (combination of elements 32, 64, and 72). In Milliman et al. reference, the firing trigger (24) is pulled proximally towards the stationary portion of the handle (22), which forces the driving pawl (42 and 43) distally into engagement with the toothed rack (48) of the

"firing mechanism" (46). The "firing mechanism" in turn forces the "firing bar" (52) in a distal direction to perform the stapling function at the end effector (17).

Regarding claim 1, the indicator member is considered to be rotationally related to the firing mechanism in the manner that when the firing trigger is squeezed, it rotates about pivot pin (38). Upon rotation of the handle, the firing mechanism moves in conjunction with the indicator member.

Regarding claim 2, the actuator is interpreted to be the portion of the indicator member indicated by reference numerals 64 and 72 of Milliman et al. reference. The indicator member is coupled to the firing mechanism by shaft (62). The return motion is created when a proximal force is placed on the knobs (32) of the indicator member by hand, which puts a proximal force on release plate (64), thereby disengaging the driving pawl from the toothed rack of the firing mechanism. The spring (72) applies a proximal bias on the firing mechanism, therefore simultaneously releasing the driving pawl from the toothed rack and moving the firing mechanism proximally to the unfired position by simply forcing the knobs (32) in a proximal direction.

Regarding claim 3, the housing is indicated by reference numeral 36 and the knob is exposed via longitudinal slots (34) in the housing, through which shaft (62) passes which is connected to the knobs (32).

Regarding claim 4, the lever is interpreted to be the inner portion of knob (32), which extends slightly longitudinally inside the shell of the knob (see Figure 4). The knobs in conjunction with the levers are capable of being actuated by hand.



Regarding claim 5, the firing operation is capable of occurring if the entire structure of the indicator member were removed (disengaged) from the firing mechanism.

Regarding claim 8, the "end effector" is a stapling device.

Regarding claim 9, the "elongate channel" of the end effector of Milliman et al. reference is illustrated in Figure 21, reference numeral 218. The "anvil" (204) is pivotally mounted to the channel. The "staple cartridge" (220) is received in the elongate channel. The firing member distally terminates in a firing bar (52) at reference numeral 47 on the firing mechanism (46).

9. Claims 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Milliman et al. (5,865,361). Milliman et al. reference discloses a surgical stapling apparatus comprising an "elongate implement portion" (14, 16 and 17), a "firing mechanism" (46), a "firing trigger" (24), and an "indicator member" (combination of elements 32, 64, and 72). In Milliman et al. reference, the "firing trigger" (24) is pulled proximally towards the stationary portion of the handle (22), which forces the "firing member" (42 and 43) distally into engagement with the toothed rack (48) of the "firing mechanism" (46). The "firing mechanism" in turn forces the "firing bar" (52) in a distal direction to perform the stapling function at the end effector.

Regarding claim 11, the firing member (42 and 43) communicates with the elongate implement portion (14, 16 and 17) via the firing mechanism (46) and the firing bar (52). The indicator member comprises means for manually applying a retraction

force to the firing member by putting a proximal force on the knobs (see explanation of claim 2 rejection above).

10. Claims 13-15 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Milliman et al. (5,865,361). Milliman et al. reference discloses a surgical stapling apparatus comprising an "elongate implement portion" (14, 16 and 17), a "handle" (12), a "firing member" (42 and 43), a "firing mechanism" (46), a "firing trigger" (24), and a "manual retraction member" (combination of elements 32, 64, and 72). In Milliman et al. reference, the "firing trigger" (24) is pulled proximally towards the stationary portion of the handle (22), which forces the "firing member" (42 and 43) distally into engagement with the toothed rack (48) of the "firing mechanism" (46). The "firing mechanism" in turn forces the "firing bar" (52) in a distal direction to perform the stapling function at the end effector.

Regarding claim 14, the lever is interpreted to be the inner portion of knob (32), which extends slightly longitudinally inside the shell of the knob (see Figure 4). The knobs in conjunction with the levers are capable of being actuated by hand.

Regarding claim 15, the firing operation is capable of occurring if the entire structure of the indicator member were removed (disengaged) from the firing mechanism.

Regarding claim 18, the "end effector" is a stapling device.

Regarding claim 19, the "elongate channel" of the end effector of Milliman et al. reference is illustrated in Figure 21, reference numeral 218. The "anvil" (204) is pivotally mounted to the channel. The "staple cartridge" (220) is received in the

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elongate channel. The firing member distally terminates in a firing bar (52) at reference numeral 47 on the firing mechanism.

Regarding claim 20, Milliman et al. reference discloses the device is suited for endoscopic procedures (see Column 6, Lines 13-17).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Milliman et al (5,865,361) in view of Johnson et al. (6,010,054). Milliman et al. reference discloses a surgical stapling apparatus comprising an "elongate implement portion" (14, 16 and 17), a "firing mechanism" (46), a "firing trigger" (24), and an "indicator member" (combination of elements 32, 64, and 72). In Milliman et al. reference, the "firing trigger" (24) is pulled proximally towards the stationary portion of the handle (22), which forces the "firing member" (42 and 43) distally into engagement with the toothed rack (48) of the "firing mechanism" (46). The "firing mechanism" in turn forces the "firing bar" (52) in a distal direction to perform the stapling function at the end effector. However, Milliman et al. reference does not disclose that a closure means that allows opening and closing of the implement portion are separate from the firing motion. Attention is drawn to Johnson et al. reference, which teaches the use of a manual closure (28) separate from the firing motion for increased control (ability to reposition the end effector multiple times

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before properly firing a staple) and prevention of accidental staple firing during positioning. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a manual closure device, as taught by Johnson et al. reference, with the Milliman et al. device to open and close the end effector separately from the firing motion for increased control (ability to reposition the end effector multiple times before properly firing a staple) and prevention of accidental staple firing during positioning.

***Allowable Subject Matter***

12. Claims 6, 7, 16, and 17 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 8:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ryan Severson  
September 13, 2006



ANH TUAN T. NGUYEN  
SUPERVISORY PATENT EXAMINER

9/18/06